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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,926	09/29/2003	Gregory L. Sundberg	279.666US1	7372
21186	7590	08/03/2006	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			SMITH, TERRI L	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/673,926	<b>Applicant(s)</b> SUNDBERG, GREGORY L.	
	<b>Examiner</b> Terri L. Smith	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-26 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-6 and 8-26 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 05 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

***Response to Arguments***

1. Applicant's arguments with respect to claims 1–6 and 8–23 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

3. Claims 1–23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 1, 8, 15, and 19 are vague. It is unclear how the fixation helix forms a drive mechanism. Does it form the mechanism simply by attaching the helix to the piston or by some other way? The Examiner is requesting the Applicant to state on the record how the fixation helix forms a drive mechanism. The Examiner has interpreted the drive mechanism as just the connection of helix to piston.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 8, 9, 10, 12, and 14–17 are rejected under 35 U.S.C. 102(b) as being anticipated by Li, U.S. Patent 5,259,395.

Art Unit: 3762

6. Regarding claims 1, 8, 15, Li discloses a lead body extending from a distal end to a proximal end (Fig. 1); a conductor disposed within the lead body (36); a piston movably disposed within a lead body/housing (40, rotor body); and a fixation helix (18) supported by at a first portion of fixation helix/coupled with a piston along a first longitudinal portion of a fixation helix (Fig. 2), a first portion of a fixation helix supported by a piston/coupled with the piston (connection of 18 at 40) forming a drive mechanism that advances/and retracts a fixation helix (Figs. 2–3); and a housing portion disposed near a distal end of a lead body (32), a housing portion including a guide/guide disposed within an inner surface of a housing/extending from an inner surface of a housing (72, guide pin; 74, guide screw) adapted to guide a drive mechanism disposed on an inner surface thereof; a housing disposed near a distal end of a lead body (portion of claim 8) (32); a piston electrically coupled with a conductor (portion of claim 15) (column 4, lines 15–18); a guide adapted to interact with a first portion of a fixation helix (portion of claim 15) (Figs. 2–3).

7. Li discloses a first portion of a fixation helix is coupled with a piston (claim 2) (connection of 18 at 40); a guide is a helical guide (claim 9) (72 and 74 are helical guides in that they guide by engaging a helical groove; column 5, lines 6–10); a helical guide is a segmented helical guide (claim 10) (column 6, lines 65–66 and 62–64); a fixation helix has an inner diameter and a piston has an outer diameter, and an outer diameter is greater than an inner diameter prior to coupling a fixation helix with a piston (claim 12) (Figs. 2 and 4); a fixation helix/active fixation helix is electrically coupled with a conductor (claims 14 and 16) (column 4, lines 15–18); an active fixation helix is recessed within a portion of a piston (claim 17) (Figs. 2–

Art Unit: 3762

4); a stop adapted to prevent over extension of a fixation helix from a lead body, a stop disposed around a portion of a piston (claim 15) (column 5, lines 18–21).

8. Claims 1–6, 8, 9, 11–14, and 19–23, are rejected under 35 U.S.C. 102(b) as being anticipated by Bisping, U.S. Patent 4,282,885.

9. Bisping discloses a lead body extending from a distal end to a proximal end (Fig. 1); a conductor disposed within a lead body (18); a piston movably disposed within a lead body/housing (Figs. 3–7, elements 13 and 23, protective core); and a fixation helix (2, 22) supported by at a first portion of fixation helix/coupled with a piston along a first longitudinal portion of a fixation helix (Figs. 3–7), a first portion of a fixation helix supported by a piston/coupled with a piston forming a drive mechanism that advances/and retracts a fixation helix (Figs. 3–5, the working of the connection of elements 13, 10, 11, and 4; Figs. 6–7, the working of the connection of elements 23, 28, 29, 20, and 21); and a housing portion disposed near a distal end of a lead body (19), a housing portion including a guide/guide disposed within an inner surface of a housing/extending from an inner surface of a housing (24, guide sleeve) adapted to guide a drive mechanism disposed on an inner surface thereof; rotating a fixation helix (column 6, lines 31–38 and 55–59); longitudinally driving a fixation helix with a drive mechanism (Figs. 3–7; column 3, lines 9–10), including moving portions of a fixation helix along a guide (Fig. 6, elements 24 and 22).

10. Bisping discloses a first portion of a fixation helix is coupled with a piston (claims 2 and 23) (connection of 12 and 13; connection of 22 and 23); a piston has a recess wrapped around an outer surface thereof such that one or more portions of a recess are separated from one another

Art Unit: 3762

by a non-recessed portion (26, helical groove), and at least a portion of a first portion of a fixation helix is disposed within a recess (claim 3) (Fig. 6); a recess has a helical shape (claim 4) (26); a recess has a first width and a first width is less than a diameter of a first portion of a fixation helix (claim 5) (Fig. 4; column 5, lines 42–44); approximately 1/3 to 1/2 of a diameter of a fixation helix is disposed within the recess/such that successive turns of a fixation helix are separated by a non-recessed piston portion (claims 6 and 21) (Figs. 3 and 6); a guide is a helical guide (claim 9) (72 and 74 are helical guides in that they guide by engaging a helical groove; column 5, lines 6–10); a fixation helix is coupled with a piston along a recess extending inward from an outer surface of a piston, a first portion of a recess separated from a second portion of a recess by a non-recessed piston portion (claim 11) (Figs. 3 and 6); a fixation helix has an inner diameter and a piston has an outer diameter, and an outer diameter is greater than an inner diameter prior to coupling a fixation helix with a piston (claim 12) (Figs. 3 and 6); a fixation helix is coupled with a piston along a helical recess within a piston (claim 13) (Figs. 3 and 6); a fixation helix/active fixation helix is electrically coupled with a conductor (claims 14) (column 6, lines 12–15); recessing at least a part of a first portion of a fixation helix within a piston such that a non-recessed portion of a piston separates successive turns of a fixation helix (claim 20) (Fig. 6); recessing at least a part of a first portion of a fixation helix within a helical groove of a piston (claim 22) (Fig. 6).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 15–18, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping and in view of Li, U.S. Patent 5,259,395.

13. Regarding claim 15, Bisping discloses a conductor (Fig. 6, element 18); an active fixation helix supported by a piston at a first portion of a fixation helix (Figs. 3–7), a first portion of a fixation helix supported by a piston forming a drive mechanism that longitudinally advances and retracts a fixation helix (Figs. 3–5, the working of the connection of elements 13, 10, 11, and 4; Figs. 6–7, the working of the connection of elements 23, 28, 29, 20, and 21); and a housing including a guide therein, a guide extending from an inner surface of a housing and adapted to interact with a first portion of a fixation helix (24, guide sleeve). Bisping discloses a piston coupled with a conductor (Fig. 6, elements 22 and 18), but not that a piston is electrically coupled with a conductor. However, Li discloses a piston is electrically coupled with a conductor (column 4, lines 15–18) to ensure effective delivery of therapy after implanting the lead. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bisping to include a piston is electrically coupled with a conductor, as taught by Li to ensure improved delivery of therapy to a patient.

14. With respect to claim 16, Bisping discloses an active fixation helix is coupled with a piston (Fig. 6, elements 22 and 23), not that an active fixation helix is electrically coupled with a piston. However, Li discloses an active fixation helix is coupled with a piston (Figs. 2–3; column 4, lines 15–18) to ensure effective delivery of therapy after implanting the lead.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bisping to include an active fixation helix is

Art Unit: 3762

electrically coupled with a piston, as taught by Li to ensure improved delivery of therapy to a patient.

15. Bisping discloses an active fixation helix is recessed within a portion of a piston (claim 17) (Fig. 6); an active fixation helix is mechanically coupled with a piston via one or more recessed groove portions separated by a non-recessed piston portion (claim 18) (Fig. 6); a fluoromarker coupled with a portion of a housing (claim 26) (24, made of Eligiloy which is a Co-Cr-Ni-Mo metal alloy detectable by X-ray).

16. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li or Bisping as applied to claim 1 above and in view of Berthelsen et al., U.S. Patent 5,002,067.

17. Regarding claim 24, Bisping and Li disclose the essential features of the claimed invention as described above except for a housing portion comprises a molded component. However, Berthelsen et al. disclose a housing portion comprises a molded component (Fig. 1, element 10, molded plastic electrode head) to provide effective structural strength and integrity for housing the fixation helix. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Li or Bisping to include a housing portion comprises a molded component, as taught by Berthelsen et al. to improve lead strength and integrity during implantation and subsequent therapy delivery.

### *Conclusion*

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



Art Unit: 3762

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
TLS

July 27, 2006

27 July 2006

  
Primary Exam  
George E. Smith  
7/31/06